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510(k) Summary

As Required by 21 section 807.92 (c)

1-Submitter Name: Klimamed® Technologie Medizingeräte GmbH
2-Address: Oderstr 3 D-71083
Herrenberg GERMANY
3-Phone: (011) 49-7032-83190
4-Fax: (011) 49-7032-83290
5-Contact Person: Thomas Schneider, quality inspector
6-Date summary prepared: July 21st, 2004
7- Official Correspondent: Mansour Consulting LLC
8- Address: 1308 Morningside Park Dr
Alpharetta, GA 30022 USA
9- Phone: (770) 777-4146
10- Fax (425) 795- 9341
11- Contact person: Jay Mansour, president
12-Device Trade or Proprietary Name: Klimamed® Thermal Blankets, including Arm-Shoulder West Thermal Blanket and Leg Warmer Thermal Blanket
13-Device Common or usual name: Thermal blankets and controller
14-Device Classification Name: System, Thermal regulating
15-Substantial Equivalency is claimed against the following device:

- Klimamed® Thermal Mats, 510k # K011859 (refer to appendix 2)

16-Description of the Device:

DESCRIPTION/INDICATION FOR USE by physicians in clinics and hospitals

This device is an external thermal regulating system consisting of blankets that are placed in contact with the patient, and a temperature controller and is to warming the patient's temperature using carbon technology between 30 and 40 °C (86 and 104°F). The function of the device is heating, not cooling.
The heating element and sensor are both embedded inside the blankets. Four blanket sizes are available:

1- 100 Watts, Pediatric: 1.0 by 0.65 meters (3.3 by 2.17) and 3mm high (0.12 inches) weighing 0.9 kgs (Product code WD-01-100)
2- 140 Watts, Adult: 2.0 by 1.35 meters (6.6 by 4.5 ft) and 3mm high (0.12 inches) weighing 2.0 kgs (Product code WD-01-200)
3- 40 Watts, Arm Shoulder: 1.5 meters (5.0 ft) and 3mm high (0.12 inches) weighing 1.0 kg (Product code 150-AW)
4- 50 Watts, Leg Warmer: 0.95 meters (3.17 ft) and 3mm high (0.12 inches) weighing 1.2 kgs (Product code 100-DB)

The device is intended to warming pre-set body temperature as determined by the physician. It can also be utilized to warming normal body temperature during surgical procedures. It is indicated for use in hospital invasive and coronary care units, in operating, recovery and emergency rooms, in burn units, and on medical / surgical floors. The device has heating capability, not cooling.

17-Intended use of the device:

The device is intended to warming pre-set body temperature as determined by the physician. It can also be utilized to warming normal body temperature during surgical procedures. It is indicated for use in hospital invasive and coronary care units, in operating, recovery and emergency rooms, in burn units, and on medical / surgical floors. The device has heating capability, not cooling.

18-Safety and Effectiveness of the device:

This device is safe and effective as the other predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 19 below)

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19-Summary comparing technological characteristics with other predicate device:

Please find below a tabulated comparison supporting that **Klimamed® blanket & controller** is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency detailed chart path is attached.

REFER TO MAIN SUBMISSION FOR DETAILED INFORMATION

FDA file reference number	510k K011859
Attachments inside notification submission file	510k summary print out
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Identical
Target population	Identical
Design	Similar
Materials	Similar
Performance	Identical
Sterility	Identical (not applicable)
Biocompatibility	Similar
Mechanical safety	Identical
Chemical safety	Identical
Anatomical sites	Identical
Human factors	Identical
Energy used and/or delivered	Identical
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Identical
Electrical safety	Identical
Thermal safety	Identical
Radiation safety	Identical

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 2 2004

Klimamed® Technologie Medizingerate GmbH
c/o Mr. Jay Mansour
Mansour Consulting LLC
1308 Morningside Park Drive
Alpharetta, GA 30022

Re: K031728
Klimamed® Thermal Blankets, Including Arm Shoulder West Thermal Blanket and Leg Warmer Thermal Blanket
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulation System
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: July 21, 2004
Received: August 13, 2004

Dear Mr. Mansour:

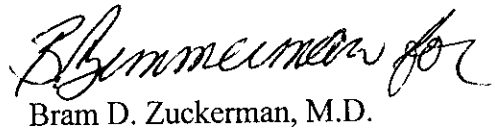
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K031728

Device Name: THERMAL BLANKETS AND CONTROLLER

Indications For Use:

THERMAL BLANKETS AND CONTROLLER
1- 40 Watts Arm Shoulder blanket and controller
2- 50 Watts Leg Warmer blanket and controller
3- 100 Watts Thermal pediatric blanket and controller
3- 140 Watts Adult Thermal blanket and controller

The device is intended to warming pre-set body temperature as determined by the physician. It can also be utilized to warming normal body temperature during surgical procedures. It is indicated for use in hospital invasive and coronary care units, in operating, recovery and emergency rooms, in burn units, and on medical / surgical floors. The device has heating capability, not cooling.

Prescription Use ✔ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K031728